












The Urogynecology Section of the Polish Society of Gynecologists and Obstetricians Guideline on the use of urodynamic testing in gynecological practice

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ABSTRACT

Objectives: The aim was to present an interdisciplinary Guideline of the Urogynecology Section of the Polish Society of Gynecologists and Obstetricians (PSGO) for the use of urodynamics (UDS) in the diagnostic process of patients with lower urinary tract symptoms (LUTS) based on the available literature, expert knowledge, and everyday practice.

Material and methods: A review of the literature concerning the use of UDS in women, including current international guidelines and earlier recommendations of the PSGO Urogynecology Section, was conducted.

Results: Urodynamic testing allows to make the urodynamic diagnosis which, nevertheless, remains to be the preliminary diagnosis. Medical history, physical examination, and detailed analysis of the previous test results (laboratory, imaging, endoscopic) need to be taken into consideration before making the final diagnosis. Urodynamic testing before surgical treatment of SUI is allowable, but the decision remains at the discretion of the physician. Urodynamic testing is not necessary before primary surgical treatment of uncomplicated SUI, but it has been demonstrated to optimize the therapeutic methods in complicated SUI. The significance of UDS in the diagnostic process of patients with overactive bladder symptoms, voiding dysfunction, and bladder outlet obstruction was discussed.

Conclusions: Urodynamic testing is a vital element of the urogynecological diagnostic process. The scope of UDS should reflect the individual needs and symptoms of each patient and be based on the current guidelines, expert knowledge and experience of the physician, indications, and eligibility, as well as additional test results of the affected patients. Due to formal and legal requirements, PSGO, in this Guideline, wishes to emphasize the need for an individualized approach to both, test performance and result interpretation.

Key words: urodynamics, stress urinary incontinence, overactive bladder, voiding dysfunction, bladder outlet obstruction, guidelines

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INTRODUCTION

Urodynamics (UDS) is a collective term used to describe tests which evaluate the function of the lower urinary tract, including bladder and urethral pressure, urethral flow rate, and electromyographic measurements.

UDS includes uroflowmetry, cystometry with stress tests (cough test and Valsalva maneuver) — with or without pressure-flow test, resting and cough urethral pressure profilometry, electromyography, and video-urodynamics [1, 2]. These functional tests allow for the assessment of the bladder contractile function, urethral resistance and continence. The main indication for urodynamic testing is a specific UDS question. The choice of the urodynamic components depends on the clinical status of the patient and the experience of the physician.

Based on UDS, urodynamic diagnoses are made, which may not be equivalent to the clinical diagnosis, as they only determine the state of the urinary tract recorded in a given measurement. Importantly, any of the urodynamic tests may generate false positive and false negative results and the tests are characterized by a certain variability of observation in recognizing different conditions. Therefore, urodynamic test results should not be perceived as the final diagnosis. Data from medical history, physical examination, and earlier test results (e.g., laboratory, imaging and endoscopic), are necessary to interpret the results.

Objectives

The aim was to develop a Guideline on the use of urodynamic testing in the diagnostic process of patients with lower urinary tract symptoms (LUTS), based on the available literature reports, expert knowledge, and everyday practice.

MATERIAL AND METHODS

The literature, including current international guidelines, was reviewed for the following content: the use of UDS in the diagnostic process, patient eligibility for treatment, and the efficacy of stress urinary incontinence (SUI), overactive bladder/detrusor overactivity, voiding dysfunction, and bladder outlet obstruction therapies. Data quality, risk-to-benefit ratio, availability of the resources in Poland, and the consensus of the experts were analyzed for all guidelines. Recommendations with uncertain risk-to-benefit ratio and discrepancies between research results and expert opinions were excluded.

REVIEW OF THE LITERATURE, INCLUDING GUIDELINES

UDS in patients with SUI

The significance of UDS in the process of determining patient eligibility for the surgical treatment of SUI was evaluated in the VALUE and VUSIS I and II randomized clinical

trials. The effects of surgical treatment in patients with and without pre-surgery UDS were compared [3–5]. After these results were published, the number of urodynamic tests decreased. The VALUE trial found no correlation between UDS and higher efficacy of the surgical treatment of uncomplicated SUI, as defined by the American Urogynecologic Society (AUGS) and the American College of Obstetricians and Gynecologists (ACOG). However, many experts have raised concerns about the design of these two RCTs and their subsequent interpretation. The effects were evaluated solely with questionnaires and the cough test. The surgeries were mostly performed by physicians in training, not by experts. Surgery types and eligibility criteria were not described [3]. Similar conclusions were reported after the VUSIS I trial, which had only 59 participants. In the VUSIS II trial, with 109 patients, no evidence was found of reduced efficacy of mid-urethral sling implantation in patients with SUI who had not undergone UDS before surgery. The sample size in both VUSIS trials was relatively small. Also, there were significant inter-center differences in terms of indications, planning and techniques for SUI management, so the effects of UDS on the surgical outcome varied to some extent. Notably, the VALUE trial included only women with uncomplicated SUI [4–6].

Urodynamic testing is not necessary before the primary surgical repair of uncomplicated SUI if the symptoms and normal urethral mobility were confirmed by medical history and if the cough test was positive. The following will need to be excluded: clinically significant vaginal and uterine prolapse during the Valsalva maneuver, recurrent urinary tract infections, and post-void urine retention [7–9]. According to the AUGS criteria, patients with uncomplicated SUI have a history of involuntary urine leakage on effort and coughing but no evidence of recurrent urinary tract infections, hematuria, incomplete emptying, chronic urinary retention, and absence of voiding symptoms such as hesitancy, slow stream, intermittency, and straining to void. These patients have no prior anti-incontinence surgery or extensive pelvic surgery, and no illnesses which might affect the urinary tract function, e.g., neurologic diseases. Their physical examination shows no signs of post-void residual (PVR) volume of > 100 mL or POP beyond the hymen. These patients also have normal urethral mobility and absence of urethral abnormality [7, 8, 10, 11].

Among women with SUI, uncomplicated SUI is diagnosed in 5–36% of the cases [12–15]. In the VALUE trial, 66% of the patients were excluded from the study for not meeting the eligibility criteria for uncomplicated SUI [3].

UDS in patients with UI, especially with complicated SUI, has been proven to optimize the therapeutic decision [16–21]. A multicenter trial, which included 2053 women, demonstrated that urodynamic testing led to the reevalua-

tion and change of the original UI diagnosis in 74.6% of the patients with complicated and 40% with uncomplicated SUI [18]. Management alterations based on the UDS results occurred in 62% of the patients, and the sling surgery was abandoned in 15% of the cases [18]. UDS found features of detrusor overactivity [22] and functional bladder outlet obstruction in as many as 20% of the patients with uncomplicated SUI diagnosed based on medical history [13, 19]. Voiding dysfunction, which is associated with higher risk of sling surgery failure [23], has been demonstrated in 10% of the women with uncomplicated SUI [3].

The authors of this Guideline believe that urodynamic testing is not necessary before the surgical repair of uncomplicated SUI if the findings do not affect the type of the procedure and if the probability of a successful outcome is high [6]. Urodynamic testing is allowable in all patients before surgical repair of SUI [24–26]. The decision is subjective and based either on the experience of the physician or on the formal and legal requirements. Data from the randomized trials on the possibility of omitting UDS before elective surgical repair of SUI apply only to patients with uncomplicated SUI. Pre-operative urodynamic testing may be beneficial in women with complicated SUI as it allows to determine the risk for failure of the standard surgical treatment [7, 16–19]. Patients with uncertain UI type or those with the suspicion of overflow incontinence may also benefit from UDS before surgery [24].

In various urogynecological centers, the diagnostics of the intrinsic sphincter deficiency (ISD) is performed during UDS. There are no standard diagnostic procedures for ISD. Bladder pressure at which leakage occurs (VLPP, Valsalva Leak Point Pressure) is measured during cystometry, during the Valsalva maneuver. The maximal urethral closure pressure (MUCP) is tested during urethral pressure profilometry (UPP) at rest [4, 27].

UDS in the evaluation and conservative treatment of the overactive bladder syndrome

Overactive bladder syndrome (OAB) is a symptom complex associated with the lower urinary tract, *i.e.*, urgency, frequency, nocturia and/or urgency urinary incontinence. OAB is not a separate disease entity and, as such, is not registered in the international classification of diseases. Nevertheless, the term 'overactive bladder syndrome' is commonly used by physicians in medical documentation and in the literature, in accordance with the International Continence Society (ICS) definition [28], and it is also a reimbursement criterion for certain drugs in Poland. OAB is suggestive of, but not consistent with, detrusor overactivity. The diagnosis can be made after ruling out urinary tract infections, urolithiasis and urinary tract cancers, bladder outlet obstruction, and diseases of the nervous system. Thorough medical history

should be taken, and urinalysis should be performed in the diagnostic process due to urgency and frequency [29, 30]. The decision to include post-void residual volume, urine culture, or micturition diary into the evaluation should be left to the discretion of the physician. Contrary to some opinions [29, 30], the authors of this Guideline believe that an ultrasound examination, combined with the evaluation of post-void residual volume, should be incorporated into the initial diagnostic process to exclude other causes of the symptoms. However, ultrasound parameters of the bladder such as wall thickness are not useful for the diagnosis of detrusor overactivity [2]. Our recommendation is based, among others, on the following: 1) availability of ultrasound devices in gynecological and urological offices, 2) age-dependent increase in the risk for bladder tumor (mean 0.5%), 3) vesical calculi as the possible cause of such symptoms, 4) non-invasive nature of ultrasound testing [31, 32].

The role of UDS in OAB diagnosis is limited to specialist management in selected, complicated cases. Urodynamic testing is not recommended at the initial stages of OAB diagnosis [30], or as part of the qualification for pharmacological treatment due to insufficient sensitivity and specificity of the tests regarding idiopathic detrusor overactivity. Only about half of the patients with non-neurogenic detrusor overactivity diagnosed with UDS experience bothersome urinary urgency [33]. At the same time, only 50–60% of women with typical OAB symptoms present with uncontrolled detrusor contractions recorded during the filling phase of cystometry [34, 35]. Other arguments against routine UDS in patients with OAB include low inter-observer reproducibility of the result [36], and no evidence of a relationship between the prevalence or severity of detrusor overactivity symptoms and treatment effects [20, 37].

UDS may play a role in the diagnostic process after all pharmacological treatment options for OAB have been exhausted, in cases of OAB concomitant with other pelvic floor disorders for example: urinary incontinence, voiding dysfunction, pelvic organ prolapse, pain, or with inconclusive medical history and/or symptoms. It is not possible to list the conditions when urodynamic testing is indispensable. The decision to perform urodynamic tests remains subjective and may reflect the experience of the physician or may be based on the formal and legal requirements.

The role of UDS before invasive OAB treatment *UDS before BTX injections*

Botulinum toxin (BTX) injection therapy has been registered and recognized as an effective management of drug resistant OAB. The main risks associated with the procedure include voiding disorders, urinary retention with the need for self-catheterization, and urinary tract infections. However, in the group of women receiving 100 IU of onabotulinum-

toxin A, these complications have been reported to be rare ($\leq 5\%$) [38]. The diagnosis of detrusor overactivity using UDS has not been proven to be related with higher efficacy of this therapy. Therefore, patients with OAB symptoms, without detrusor contractions during the filling phase, are as likely to benefit from BTX therapy as those with confirmed overactivity [39]. Other urodynamic observations, e.g., detrusor underactivity and bladder outlet obstruction, may increase the risk for voiding dysfunction after surgery [40]. Still, it is not an indication for routine UDS before BTX therapy, also within the current clinical trial framework [41]. The Italian expert panel concluded that UDS should be obligatory in patients with neurogenic detrusor overactivity or with a suspicion of voiding dysfunction. Otherwise, urodynamic testing is not necessary. They also recommended to perform at least a single uroflowmetry with PVR volume evaluation to exclude voiding dysfunction before BTX therapy [42]. The authors of this Guideline believe that an ultrasound test, with simultaneous evaluation of the post-void residual volume, should be considered to rule out other sources of the symptoms.

UDS before sacral neuromodulation

Sacral neuromodulation (SNM) is an invasive treatment of therapy resistant detrusor overactivity, voiding dysfunction unrelated to bladder outlet obstruction, and fecal incontinence. It has also been experimentally used to treat neurogenic dysfunctions and chronic pelvic pain syndrome. Percutaneous sacral nerve stimulation, routinely performed before the final implantation, is the only predictor of therapy efficacy. No relation has been found between detrusor overactivity recorded in UDS and the efficacy of sacral neuromodulation [43]. Although in some medical centers urodynamic testing is included in the eligibility process, it is not standard management and no cases of better treatment outcomes of typical, uncomplicated, resistant to pharmacotherapy OAB after routine UDS have been reported [44]. In their statement, the ICS expert panel concluded that urodynamic testing was more justified during the eligibility process in patients with neurogenic dysfunction, comorbid SUI, or voiding dysfunction, as well as after prior procedures affecting the function of the lower urinary tract, e.g., implantation of a mid-urethral sling [45].

UDS before bladder augmentation

Ileocystoplasty and other methods of bladder augmentation are highly invasive surgical procedures, with significant risk of severe complications. Their applicability in the therapy of idiopathic OAB remains marginal and is limited to extreme cases of low volume and low compliance of the bladder. Due to the risk of severe surgical complications associated with opening of the gastroin-

testinal tract and integrating the intestinal mucosa into the urinary tract, bladder augmentation is not the method of choice for therapy resistant OAB, despite most satisfactory functional results [46, 47]. Urodynamic testing is a vital component of the eligibility process for this form of treatment due to the need to confirm severe bladder dysfunction.

UDS in patients with bladder outlet obstruction and voiding dysfunction

The prevalence of voiding dysfunction among women has been estimated at approximately 5%, but even in that group voiding dysfunction as the dominant symptom is reported only by a small number of patients. Among patients who underwent UDS, the prevalence of impaired bladder emptying has been estimated at 6–30%, depending on the criteria. Numerous studies demonstrated bladder outlet obstruction to be an additional or unexpected urodynamic symptom in women undergoing UDS for reasons other than voiding dysfunction [2, 48, 49]. There are no strict indications for urodynamic testing in the event of obstructive symptoms. The authors of this Guideline advise to take the post-void residual volume of > 100 mL in several measurements or maximum flow rate in non-invasive uroflowmetry < 15 mL/s as an indicator of voiding dysfunction. If the cause of the obstruction remains unclear after the physical and the ultrasound tests, UDS may be helpful in confirming or excluding bladder obstruction or detrusor underactivity. Still, urodynamic testing does not allow to determine the cause of the obstruction [2, 50, 51].

Detrusor underactivity is defined as the contraction of reduced strength and/or duration, resulting in prolonged bladder emptying or failure to achieve complete bladder emptying. Like bladder outlet obstruction, the diagnosis of detrusor underactivity in women has not yet been standardized.

The following are used in the diagnostic process of detrusor underactivity:

- a) video-urodynamic test,
- b) pressure-flow test,
- c) uroflowmetry,
- d) stop-test (a modification of the pressure-flow test used to evaluate detrusor strain during isovolumetric contraction, i.e., during urethral closure achieved by catheter or sphincter contraction),
- e) voiding test with continuous urethral occlusion,
- f) the PIP (1) parameter [projected isovolumetric pressure, $PIP(1) = p_{det}(Q_{max}) + Q_{max}$],
- g) extremely low detrusor pressure (e.g., < 10 cm H_2O) co-existing with extremely low urinary flow rate [2, 50–52].

Urodynamic diagnosis of bladder outlet obstruction and detrusor underactivity in women is objective to some

extent, but it also depends on the physician who interprets the results, especially in borderline cases. Therefore, it is essential to analyze urodynamic results together with the physical examination and imaging test results [2, 53].

CONCLUSIONS

Urodynamic testing is an essential element of urogynecological diagnostic process. The indications for UDS as well as the scope of testing are tailored to the needs of each patient. They result from the knowledge and experience of the physician, patient symptoms and indications, additional test results, current guidelines, as well as formal and legal requirements.

The Polish Society of Gynecologists and Obstetricians issued this Guideline for the therapeutic options, with emphasis on the need for an individualized approach to urodynamic testing and result interpretation.

Conflict of interest

None.

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